



NDA 21-225/S-002

Berlex Laboratories, Inc.
Attention: Nancy Konnerth
Manager, Advertising and Labeling Drug Regulatory Affairs
340 Changebridge Road
P.O. Box 1000
Montville, NJ 07045

Dear Ms. Konnerth:

Please refer to your supplemental new drug application dated October 3, 2001, received October 4, 2001, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Mirena® (levonorgestrel-releasing intrauterine system).

This "Changes Being Effected in 30 days" supplemental new drug application provides for the Spanish translation of the Physician and Patient booklets and the following editorial correction to the Patient Consent Form which appears on the back of the Patient booklet.

"The patient has signed this consent form in my presence after I ~~consulted~~ counseled her and answered her questions."

We have completed the review of this supplemental application and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the submitted final printed labeling (package insert submitted October 3, 2001, patient package insert submitted October 3, 2001). Accordingly, the supplemental application is approved effective on the date of this letter.

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Jennifer Mercier, B.S., Regulatory Project Manager, at (301) 827-4260.

Sincerely,

{See appended electronic signature page}

Daniel Shames, M.D.
Acting Director
Division of Reproductive and Urologic Drug Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research

**This is a representation of an electronic record that was signed electronically and
this page is the manifestation of the electronic signature.**

/s/

Daniel A. Shames
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